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| 09/866,261 | 05/25/2001 | Thuy Diem Pham | TPB-001D1 | 8078 |

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| EXAMINER | |
|---|---|
| KIM, YOUNG J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/866,261 | PHAM, THUY DIEM | |
| | Examiner | Art Unit | |
| | Young J. Kim | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,6,7,13,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,13,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The present Office Action is responsive to the Amendment received on July 15, 2005.

### *Preliminary Remark*

Claims 1, 2, 6, 7, 13, 15, and 17 are pending and are under prosecution.

### *Priority*

The objection to the specification for failing to update the status of parent, non-provisional application, is withdrawn in view of the Amendment received on July 15, 2005, amending the specification.

### *Claim Rejections - 35 USC § 112*

The rejection of claims 6, 7, 13, 15, and 17 under 35 U.S.C. 112, second paragraph as being indefinite for reciting the phrase, "subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus," made in the Office Action mailed on March 17, 2005 is withdrawn in view of a careful reconsideration and in view of the arguments presented in the Amendment received on July 17, 2005.

The scope of enablement rejection of claims 6, 7, 15, and 17 under 35 U.S.C. 112, first paragraph, made in the Office Action mailed on March 17, 2005 is withdrawn in view of the Amendment received on July 17, 2005, adopting the examiner's suggestion.

### *Maintained*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 13, 15, and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on March 17, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on July 15, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants appear to rely on the previous prosecution history of a parent application, conducted by the previous Examiner, for their rebuttal. Applicants, other than the prosecution history, do not properly point out the supposed errors of the rejection.

Applicants are reminded that every application is examined on its own merits. The rejection made by the present Examiner has been articulated in the Office Action mailed on March 17, 2005. The rejection will be explained herewith.

The rejected claims employ the following:

a) an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8;

b) an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein; and

c) an oligonucleotide at least 95% identical to an oligonucleotide that hybridizes under stringent conditions to an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8; ***or*** an oligonucleotide at least 95% identical to an oligonucleotide that hybridizes to an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein.

As clearly evident, the metes and bounds of the oligonucleotide of embodiment c) are indefinite.

***Maintained***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 13, 15, and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on March 17, 2005 is maintained for the reasons of record.

The entire breadth of the claims is drawn a method involving the following oligonucleotides:

a) an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8;

b) an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein; and

c) an oligonucleotide at least 95% identical to an oligonucleotide that hybridizes under stringent conditions to an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8; ***or*** an oligonucleotide at least 95% identical to an oligonucleotide that hybridizes to an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein.

It should be reiterated that the claims are drawn to a method for detecting avian leucosis/sarcoma viruses in a poultry sample, wherein naturally occurring virus is located or detected from chicken or egg host, wherein the method is accomplished by the oligonucleotides of the above-recited embodiments.

The written description requirement ensures that, "an applicant invented the subject matter which is claimed. Further, the written description requirement for a claimed genus may be satisfied *through a* sufficient description of *a representative number of species* by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (*i.e.*, structure of other physical and/or chemical properties, functional characteristics *coupled* with a known or disclosed correlation between function and structure) (MPEP 2163 at II(A)(3)(a)(ii)).

**Response to Arguments:**

Applicants' arguments presented in the Amendment received on July 15, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants contend that contrary to the Office Action's position, the instant specification fully described the relevant species in Table 1 on page 28, from page 34-line 6 to page 39-line 4; and from page 39-line 4 to page 39-line 20 (page 8, Response), thereby disclosing a representative number of species embraced by the genus.

The entire breadth of the claims is drawn a method involving the following oligonucleotides:

a) an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8;

b) an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein; and

c) an oligonucleotide at least 95% identical to an oligonucleotide that hybridizes under stringent conditions to an oligonucleotide at least 95% identical to SEQ ID NO: 7 and SEQ ID NO: 8; ***or*** an oligonucleotide at least 95% identical to an oligonucleotide that

hybridizes to an oligonucleotide at least 95% identical to a nucleotide sequence encoding the $gp^{env}$ protein.

It should be reiterated that the claims are drawn to a method for detecting avian leucosis/sarcoma viruses in a poultry sample, wherein naturally occurring virus is located or detected from chicken or egg host, wherein the method is accomplished by the oligonucleotides of the above-recited embodiments.

Therefore, the issue at hand is whether Applicants were in possession of a genus of oligonucleotides of the above embodiments which allows the detection of naturally occurring virus (endogenous).

Applicants point to Table 1, on page 28 of the instant specification:

Table 1 discloses sets of primers which are derived from $gp85^{env}$ gene of endogenous and exogenous avian leucosis/sarcoma virus (ALSV) subgroups (page 25, lines 9-11).

The primer set identified as PU1 and PU2 are disclosed as being degenerate which allows for the general detection of avian leucosis viral subgroups A, B, C, D, and E (page 25, lines 12-13) chosen from "highly conserved regions, which flanked the *hypervariable region 1* for all avian leucosis/sarcoma virus subgroups in the $gp85^{env}$ gene." (at lines 15-17).

The primer set identified as PA1 (SEQ ID NO: 7) and PA2 (SEQ ID NO: 8) is disclosed as being specific for avian leucosis/sarcoma virus subgroup A (page 25, lines 17-20).

The primer set PA10 and PA20 is disclosed as being specific for leucosis/sarcoma virus subgroup A; the primer set PB1 and PB2 is disclosed as being specific for virus subgroup B; the primer set PC1 and PC2 is disclosed as being specific for virus subgroup C; the primer set PD1

and PD2 is disclosed as being specific for subgroup D; and the primer set PE1 and PE2 is disclosed as being specific for subgroup E.

Hence, Table 1 discloses sets of primers identified from a five subgroups of ALSV $gp85^{env}$ gene which allow for the detection of each virus subgroups A-E.

The gene encoding $gp85^{env}$ is about 2,000 nucleotides in length.

However, claims not only embrace the use of primers derived from anywhere on the entire $gp85^{env}$ gene, but nucleic acids that are homologous thereto.

Additionally, it is known that $gp^{env}$ protein can be found in a plurality of species – HPRS-103 (subgroup J; exogenous) avian leucosis virus, EBV, FeLV (feline leukemia virus), different strains ***within each of the different subgroups*** of ALV, such as strains VR-334 and 335 subgroup A; VR 657 and 658 for subgroup B, etc.

The fact that different strains are present within each of the subgroup of ALV is communicated by Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81), wherein the artisans express:

> "Three sets of degenerate oligonucleotide primers were synthesized by Microsynth, Switzerland. Primers were designed to detect ALV subgroups A to E. Regions of gp85 env gene showing the highest degree of conservation ***between different ALV strains*** were selected." (page 73, 2nd column, 1st paragraph)

The specification simply does not have description of a method employing a vast genus of oligonucleotides derived from any gene encoding $gp85^{env}$ or its homologs.

The rejection is maintained therefore.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 2, and 13 under 35 U.S.C. 103(a) as being unpatentable over Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81; IDS ref# AD) in view of Spencer et al. (Avian Disease, 1977, vol. 21, no. 3) and Bohinski et al. (U.S. Patent No. 5,976,873, issued November 2, 1999, May 17, 1995), made in the Office Action mailed on March 17, 2005 is withdrawn in view of the Amendment received on July 15, 2005, amending the claims to include a new limitation.

***Maintained***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 6, 7, 15, and 17 under 35 U.S.C. 103(a) as being unpatentable over Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81; IDS ref# AD), Spencer et al. (Avian Disease, 1977, vol. 21, no. 3) and Bohinski et al. (U.S. Patent No. 5,976,873, issued November 2, 1999, filed May 17, 1995), made in the Office Action mailed on March 17, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on July 15, 2005 have been fully considered but they are not found persuasive.

Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method comprising the steps of:

(a) isolating viral RNA from allantoic fluids of SPF eggs;

(b) RT-PCR using primer pairs ALVgp85U3/L3;

(c) detecting the presence of the virus (page 78).

The RT-PCR primers are derived from nucleotide sequence encoding $gp^{env}85$ protein (page 75, 2nd column, 1st paragraph), meeting limitation of, "an oligonucleotide having a sequence having at least 95% identical to...a nucleotide sequence encoding the $gp^{env}$ 85 protein."

Hauptli et al. also distinguish each of the subgroups A-E via determining their restriction enzyme digestion pattern on an electrophoretic gel (Table 2).

Hauptli et al. do not employ DNA sequencing for this distinction.

Hauptli et al., in isolation of RNA, employ the reagent, Trizol™ LS (page 73, 2nd column, bottom paragraph) rather than the claimed β–mercaptoethanol.

Hauptli do not extract viral RNA from egg albumen.

Bova et al. disclose a method of distinguishing between different avian leucosis/sarcoma subgroup D and subgroup A via well known nucleic acid sequencing method such as chemical cleavage and dideoxy chain termination method (page 76, 2nd column, 4th paragraph). The artisans disclose that a complete sequence was determined on both strands of DNA.

Spencer et al. disclose a well known-knowledge of leukosis virus being present in chicken eggs, their albumen, embryos, chicks, and hens (Abstract).

The use of β-mercaptoethanol in RNA isolation has been well-established in the art of nucleic acid extraction as evidenced by Bohinski et al. (column 50, lines 39-44).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the subgroup distinction step of Hauptli et al. with the nucleic acid sequencing method of Bova et al. for the following reasons.

MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success.

It is clear that Haputli et al. amplify the region of nucleic acid sequences encoding $gp^{env}$ 85 protein of avian leucosis/sarcoma virus subgroups A-E. The amplified products, which represent subgroups A-E, are disclosed as having the expected size of 371 base pairs (page 75, 2nd column, 2nd paragraph). Further, the amplified products are digested producing different restriction patterns (Table 2), evidencing the presence of different sequences between the subgroups.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success at sequencing the amplified product of Hauptli et al. in distinguishing between the different avian leucosis/sarcoma virus subgroups, as nucleic acid sequencing method had been well-established in the art and commonly employed in comparing and distinguishing nucleic acid sequences of different species, as evidenced by Bova et al.

With regard to distinguishing between endogenous and exogenous retrovirus, Hauptli et al. disclose that subgroup E is endogenous and subgroups A-D are exogenous (page 72, 2nd column, 1st paragraph). Therefore, distinguishing between each avian subgroups would necessarily allow one of ordinary skill in the art to distinguish between endogenous and exogenous retrovirus.

Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hauptli et al. with the teachings of Bohinksi et al. to extract viral RNA from samples using well-known equivalent reagent (from Trizol to mercaptoethanol). One of ordinary skill in the art at the time the invention was made

would also have been motivated to detect viral RNA from sources wherein its residence had been well-characterized, as evidenced by Spencer et al.

MPEP, at 2144.06, in discussing substitution of equivalents for the same purpose, states:

> "In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art..."

RNA extraction via use β-mercaptoethanol has been practiced in the art for quite some time, as evidenced by Bohinski et al., and therefore, the equivalency of employing β-mercaptoethanol rather than Trizol, for the same purpose – RNA extraction – has been fully established.

Applicants are advised that the claims 13, 15, and 17, while containing an embodiment to employing an oligonucleotide at least 95% identical to SEQ ID Numbers 7 and 8, also contains embodiment drawn to employing an oligonucleotide at least 95% identical to **any** nucleotide sequence encoding $gp^{env}85$ protein. As the primers employed by Hauptli et al. are designed to detect ALV subgroups A to E – i.e., derived from regions of $gp^{env}$ 85 gene (page 73, 2nd column, 1st paragraph) – said primers would necessarily contain at least 95% identity to a nucleotide sequence encoding $gp^{env}$ 85 protein.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

**Response to Arguments:**

Applicants appear to apply their arguments drawn to the rejection of claims 1, 2, and 13 to the present rejection (*see* page 12 of the Response, wherein Applicants state, "[f]or substantially the same reasons that amended claims 1 and 13...independent claims 6 and 15 are patentable over" the prior art references.

To this end, the arguments are not found persuasive.

Applicants contend that the present invention results in the detection of avian leucosis virus in albumen of chicken eggs using reverse transcription polymerase chain reaction, wherein the procedure involves:

a) isolating naturally occurring avian leucosis/sarcoma retroviruses from albumen of chicken eggs;

b) performing RT-PCR with the specified primers [PA1/PA2 (for subgroup A, PU1/PU2 (for subgroup A, B, C, D, E), PA10/PA20 (for subgroup A), PB1/PB2 (for subgroup B), PC1/PC2 (for subgroup C), PD1/PD2 (for subgroup D), PE1/PE2 (for subgroup E)];

c) direct sequencing of the RT-PCR product.

Initially, the rejected claims do not strictly employ the above-recited primers. Rather, claims 6 and 7 are non-limiting to any type of primers; and claim 15 and 17 are open to any primers derived from a gene encoding $gp85^{env}$ or its 95% homolog.

As already discussed in the rejection, Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method involving RT-PCR using primer pairs ALVgp85U3/L3, wherein the RT-PCR primers are derived from nucleotide ***sequence encoding $gp^{env}85$ protein*** (page 75, 2nd column, 1st paragraph), meeting limitation of, "an oligonucleotide having a sequence having at least 95% identical to...a nucleotide sequence encoding the $gp^{env}$ 85 protein."

With regard to the sequencing of the RT-PCR product, the rejection already stated that Bova et al. disclosed a method of ***distinguishing between different avian leucosis/sarcoma***

***subgroup D and subgroup A*** via ***well known nucleic acid sequencing*** method such as chemical cleavage and dideoxy chain termination method (page 76, 2nd column, 4th paragraph).

Hence, all of the limitation required by the instant claims are clearly met by the references, and therefore, the rejection is maintained.

***Necessitated by Amendment***

Claims 1, 2, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81; IDS ref# AD), Spencer et al. (Avian Disease, 1977, vol. 21, no. 3) and Bohinski et al. (U.S. Patent No. 5,976,873, issued November 2, 1999, filed May 17, 1995).

Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method comprising the steps of:

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Applicants are advised that the claims 13, 15, and 17, while containing an embodiment to employing an oligonucleotide at least 95% identical to SEQ ID Numbers 7 and 8, also contains embodiment drawn to employing an oligonucleotide at least 95% identical to **any** nucleotide sequence encoding $gp^{env}85$ protein. As the primers employed by Hauptli et al. are designed to detect ALV subgroups A to E – i.e., derived from regions of $gp^{env}$ 85 gene (page 73, 2nd column, 1st paragraph) – said primers would necessarily contain at least 95% identity to a nucleotide sequence encoding $gp^{env}$ 85 protein.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

## *Conclusion*

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a

general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
10/3/2005

YOUNG J. KIM
PATENT EXAMINER

yjk

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